Outcome-based pricing for pharmaceuticals

The cost of prescription drugs has steadily risen over the past few decades. According to the Centers for Medicare & Medicaid Services (CMS), in 2015 the US spent $325 billion on retail prescription drugs, or 1.8% of GDP. CMS estimates that prescription drug spending will grow by 6.3% per year over the next 10 years. The US spends significantly more than other countries on pharmaceuticals. Average spending per capita reached $1112 in the US in 2014, while the next highest spending per capita was $783 (Japan).

High prescription drug spending can be explained both by the increasing price of existing drugs and by the emergence of new drugs that are costly to develop. High drug prices are gaining national attention as the pace of increase imposes a heavy burden on insurers and threatens access to certain drugs for many Americans, even for those with insurance coverage. According to CMS data, while private insurance and CMS programs bore a large portion of the total spending on prescription drugs in 2015 (45% and 39%, respectively), consumers paid out-of-pocket 14% of the total spending.

For very expensive drugs, uncertainty about effectiveness makes payers reluctant to provide coverage. Insurers are often unwilling to pay a lot for a drug that may not work. In particular, new drugs targeting serious diseases sometimes benefit from an accelerated approval from the Food and Drug Administration (FDA) based on surrogate measures. Under this process, these drugs enter the market with uncertain evidence of clinical benefit while the manufacturer conducts post-approval trials to confirm the drug efficacy. Facing this uncertainty, insurers may decide not to cover these drugs to avoid the risk of wasting resources by paying for an ineffective drug. For example, Exondys 51 was given accelerated approval in 2016 and was priced at $300,000 per year; Anthem declined to cover the drug, while Humana decided to cover it for certain patients only [Gellad and Kesselheim 2017]. Even for drugs undergoing the regular FDA approval process, the efficacy obtained in the course of carefully designed medical trials is not always reproduced when the drug is introduced in the general population. Hence, the effectiveness of new drugs is often subject to a high level of uncertainty.

The high price tag of drugs may cause patients to forgo taking a drug they need. The Kaiser Family Foundation reports that in 2015, 24% of Americans taking prescription medicine did not fill a prescription because of the cost[1]. The risk of incurring a high out-of-pocket without necessarily obtaining the warranted health benefits further reduces the patients’ incentive to pay for the drug.

Outcome-based pricing has been proposed as a new paradigm to pay for pharmaceuticals subject to effectiveness uncertainty. The basic idea is to re-allocate the risks by making

payment contingent on whether the drug works, instead of based on volume. In 2016, Merck & Co and Eli Lilly & Co. agreed to refund the drug price if their diabetes drugs fail to reduce patients’ blood-sugar levels to pre-specified targets. Amgen Inc. agreed to do the same if patients taking a cholesterol-lowering drug suffer a heart attack or stroke. Novartis recently agreed to refund CMS the price of a $475,000 childhood leukemia drug if patients do not respond within a month of treatment. Variants of this pricing model, also known as value-based pricing, have been used in the US in a few relatively isolated instances since the mid 1990s, and more broadly in Europe. They yielded mostly disappointing results in Italy, where they were introduced over a decade ago (Navarria et al. 2015). Yet, the current US administration is reportedly considering a similar approach to tackle high drug prices. A draft executive order prepared in June 2017 includes a value-based pricing proposal (Kaplan and Thomas 2017). CMS announced in August 2017 that it is working on innovative payment arrangements for new treatments, arrangements that “may, for example, include outcome-based pricing for medicines in relation to clinical outcomes”[2]

Outcome-based pricing offers the patient and payer the advantage of shifting the risk of treatment failure to the pharmaceutical firm, eliminating for them the risk of paying for an ineffective treatment. With a lower risk-exposure, payers are more likely to offer coverage for new drugs despite the high uncertainty on their effectiveness, which would improve patients’ access to these drugs. Outcome-based pricing also offers advantages for drug manufacturers. Given the current growing pressure to justify the high prices and cost-effectiveness of new drugs, such a pricing scheme allows for more transparency on the value of new pharmaceuticals. Outcome-based pricing can also help increase a drug’s sales by securing wider coverage from insurers and by improving patient adoption of the drug due to the absence of financial risk. However, if pharmaceutical firms set a price for new drugs that is commensurate with their risk of not receiving payment, prices could increase, and outcome-based pricing could thus adversely affect patients’ access and utility, as well as the payer’s spending.

In this paper, we introduce an analytical model to determine the effect of outcome-based pricing for new brand-name pharmaceuticals. Our model captures the interaction between heterogenous risk-averse patients who bear a portion of the drug price and decide whether to obtain the drug; a payer providing coverage for the drug; and a price-setting pharmaceutical firm seeking to maximize expected profits. We consider both a traditional uniform pricing scheme, where payment is required to obtain the drug, as well as an outcome-based pricing system, where the firm receives no payment when the treatment does not achieve a pre-specified result within a certain time frame. We investigate how the drug pricing scheme

affects the patients’ access and utility, the payer’s spending, and the pharmaceutical firm’s profit. Our goal is to understand under what conditions outcome-based pricing may benefit the different stakeholders as compared with a uniform pricing system.

We find that switching the pricing system to outcome-based pricing causes a large price increase that the firm requires to compensate the lost revenue from patients whose treatment fails. When patients are risk-neutral, the expected demand, pharmaceutical firm’s profit, payer cost and patient utility are the same under the two pricing systems. When patients are risk-averse, outcome-based pricing yields a higher expected demand, firm profit, and payer cost if and only if the chance of treatment success is less than 50% (i.e., the drug is “high-risk”). Hence, a firm would only accept to participate in an outcome-based pricing system when the drug offers a low chance of success, and doing so would worsen payer expenditures compared with uniform pricing. However, we show that a transfer payment contract may be designed between payer and firm so that, when the transfer payment is implemented alongside outcome-based pricing, both firm and payer are better off than under uniform pricing. We also find that the demand under each pricing system is lower than the system-optimum demand if the co-insurance rate is low enough. Moreover, in some cases the co-insurance rate can be adjusted to coordinate the demand with the system optimum. We evaluate the performance of each pricing system numerically in terms of firm profit, payer expenditure, patient utility and total surplus based on the example of an existing drug. Our observations indicate that patient risk-aversion acts as a barrier to access to the drug. Furthermore, for a high-risk drug, outcome-based pricing has the potential to improve consumer utility, firm profit and even total surplus, but at the payer’s detriment because of a sharp price increase and demand expansion. Therefore, outcome-based pricing is unlikely to provide the solution to the issues of high drug prices and of high payer expenditures. However, modifying outcome-based pricing by adding a transfer payment between firm and payer could benefit all agents (as compared with uniform pricing), despite maintaining high prices.

References

